

Serial No.: 09/729,924  
Atty. Docket No.: P66152US0

**REMARKS**

The Office Action mailed September 7, 2005 has been carefully reviewed and Applicants note with appreciation the identification of allowable subject matter.

By this Amendment, Applicants have canceled claims 13 and 14 without prejudice or disclaimer, amended claims 1, 7 and 10, and added claims 20-23. Claims 1-12 and 15-23 are pending in the application; claims 1, 7, 10 and 20 are independent. Claims 3 and 4 have been withdrawn.

The Examiner rejected claims 1, 2 and 15-19 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,265,280 to Ammann et al. ("Ammann"), and, under 35 U.S.C. 103(a), the Examiner rejected claims 5 and 6 as being unpatentable over Ammann. The Examiner objected to claims 7-12 as being dependent on a rejected base claim but stated that claims 7-12 would be allowable if rewritten in independent form to include the limitations of the base claim and any intervening claims.

While Applicants appreciate the identification of allowable subject matter, with the clarifying of claim 1 as amended herein, claim 1 is also in condition for allowance. Favorable reconsideration thereof, as well as of new claim 20, in view of the following remarks is requested.

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As clarified in amended claim 1, the present invention is directed to a connection system for the connection of two or more sterile systems and includes at least a male connecting element forming the closed end of a first sterile, fluid-containing system and at least a female connecting element forming the closed end of a second sterile, fluid-containing system. These connecting elements can be aseptically connected to one another by *inserting the male connecting element into the female connecting element*. Each of the connecting elements has a predetermined breaking point, with the breaking points being aligned with one another when the two connecting elements are assembled, i.e., when the male connecting element is inserted within the female connecting element, so that the two breaking points form a common predetermined breaking point. By aligning the respective breaking points to form a common breaking point, the closed ends of both connecting elements can be broken off together in a single step. Once the closed ends are broken off, fluid can flow between the two connected fluid-containing systems. The sealed nature of the system is maintained because the predetermined breaking point is located *inside the fluid-containing system*. This is not shown or suggested by Ammann.

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Ammann discloses a connector having two connector elements that are designed to be virtually identical to one another and which are mechanically connected to one another. Specifically, the two parts have closing walls and are connected by sliding the parts together parallel to these walls. The walls are then melted and fused together to establish a liquid-tight connection.

In the present invention, by contrast, a *male* connecting element having a predetermined breaking point is *inserted within a female* connecting element, also having a predetermined breaking point. When their inserted relationship has been established, the breaking points are in alignment with one another such that a common break point arises *that enables both connecting elements to be broken open together*. This is not shown or suggested by the sliding engagement of the two *identical* parts of Ammann. Nor does Ammann suggest an opening mechanism other than that of *melting* the components in order to establish the liquid path in the first place. This is unlike the present invention in which the path is already present due to the aseptic connection of the male and female connecting elements, and is thereafter opened by breaking the connecting elements. Finally, Ammann does not disclose or suggest the alignment of break points on male and female connecting elements to form a common break point as is set forth in claim 1.

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For at least the foregoing reasons, claim 1 is patentable over the prior art. Favorable reconsideration and allowance thereof is requested.

Claim 20 is in condition for allowance for at least the same reasons as claim 1. Further, the prior art does not teach or suggest inserting the male connecting element into the female connecting element such that the male and female connecting elements have *an elongated nested portion*, with the closed portions of both connecting elements being adjacent one another.

Claims 7 and 10 have each been rewritten in independent form to include the underlying limitations of original claim 1 and therefore are in condition for allowance in accordance with the Examiner's indication of allowable subject matter.

Claims 2-6, 8, 9, 11, 12, 15-19 and 21-23 are in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein. Particularly, claims 11 and 12 are in condition for allowance in accordance with the Examiner's indication of allowable subject matter. Claim 21 is allowable in that the prior art does not disclose an elongated nested portion of assembled connecting elements in which a common breaking point is located approximately in a longitudinal middle thereof. Nor does the prior art teach or

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suggest predetermined breaking points formed by respective circular notches in the connecting elements, as provided in claim 22, or the placement of the notches on the inner and outer surfaces of the male and female connecting elements, respectively, as set forth in claim 23.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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